

D. Quality Assurance

## 1. Overview

The quality assurance requirements for M+C organizations were addressed in subpart D of the June 26, 1998 interim final rule. These requirements implement and are based on the provisions of section 1852(e) of the Act. Further, they incorporate the requirements of section 1851(d)(4)(D) of the Act, which provides that the information made available to Medicare beneficiaries for plan comparison purposes must include plan quality and performance indicators, to the extent available. Section 1852(e)(1) of the Act sets forth the general rule that each M+C organization must establish an ongoing quality assurance program, consistent with implementing regulations, for the health care services it provides to enrollees in the organization's M+C plan or plans. The remaining portions of section 1852(e) of the Act contain the required elements of the quality assurance program, requirements for external review, and provisions concerning the use of accreditation organizations to determine compliance with the quality assurance requirements.

## 2. Quality Assessment and Performance Improvement Requirements (§422.152)

Section 422.152 incorporates each of the explicit statutory requirements of sections 1852(e)(1) and (2) and section 1851(d)(4)(D) of the Act. Section 422.152 also includes

additional detail to clarify what an M+C organization must do to meet the statutory requirements. Sections 422.152(b) through (d) of the interim final rule set forth requirements that M+C organizations must meet with respect to M+C coordinated care plans and network MSA plans.

Section 422.152(c) requires that the organization: (1) measure and report its performance to HCFA using measures required by HCFA; and (2) for M+C coordinated care plans, achieve any minimum performance levels that may be established locally, regionally, or nationally by HCFA.

Section 422.152(d) establishes the requirements for performance improvement projects, beginning with the requirement that performance improvement projects focus on specified areas of clinical and nonclinical services. It also explains that we will set M+C organizational and plan-specific requirements for the number and distribution of these projects among the required areas. In addition, it authorizes us to direct an M+C organization to undertake specific performance improvement projects and participate in national and state-wide performance improvement projects. Section 422.152(d) reflects many of the provisions of section 1852(e)(2) of the Act.

In enacting the quality assurance provisions of the BBA, Congress recognized that not all of the quality assessment and performance improvement activities that are appropriate for a

plan with a defined provider network would be appropriate for an M+C non-network MSA plan or an M+C PFFS plan. The requirements specific to these types of plans are addressed in §422.152(e). (Note that, as discussed below and in section I.C of the preamble, section 520 of the BBRA amended section 1852(e) of the Act to apply the non-network plan requirements to PPO plans as well.)

In order to support the measurement of performance levels and the conduct of performance improvement projects, if applicable, M+C organizations offering all types of M+C plans must maintain a health information system that collects, analyzes, integrates, and reports data. This requirement is covered at §422.152(f)(1). Section 422.152(f)(2) requires that for each M+C plan an M+C organization offers, it has a process for formal evaluation, at a minimum annually, of the impact and effectiveness of the quality assessment and performance improvement program strategy with respect to services under that plan.

Comment: A number of commenters asserted that the quality assessment and performance improvement (QAPI) requirements will be difficult for M+C organizations offering M+C plans with loosely organized provider networks to meet, and will discourage such organizations from participating in the M+C program. In particular, commenters were concerned that the QAPI requirements

will deter organizations from offering MSA plans, PFFS plans, and PPO-type coordinated care plans. One commenter explained that organizations offering non-HMO plans cannot require physicians to track outcomes for these plans because the organizations do not have contracts with the physicians, making data collection and reporting infeasible. Four commenters specifically addressed the challenges facing PPOs in producing performance data and influencing provider practice patterns as required to demonstrate performance improvement. Two commenters complained that it is not appropriate to require reporting of all clinical performance indicators from the "Healthplan and Employer Data and Information Set" (HEDIS) in the case of a broad access PPO-type coordinated care plan. These and other commenters suggested that we instead establish quality standards that account for variation in organization capabilities.

Response: The BBA recognized that the structure of health plans has a direct impact on the degree to which the organizations that offer them can reasonably be expected to directly affect the health care services provided to their enrollees. As a result, the M+C statute and interim final regulations, as well as guidance implementing these provisions, have been tailored to the varying structural differences and associated capabilities of M+C organizations. As discussed in section I.C of this preamble, section 520 of the BBRA amended

section 1852(e) of the Act to revise the quality assurance requirements for PPO plans. Consistent with the commenters' concerns, the quality assurance requirements for PPO plans are now the same requirements that apply to non-network M+C MSA plans and M+C PFFS plans. Thus, while PPO plans are still considered coordinated care plans, they are treated differently than other coordinated care plans for the purposes of the M+C quality assurance requirements of §422.152, in recognition of the fact that their provider networks are subject to a lesser degree of control and accountability. The result is that M+C organizations are no longer required to conduct performance improvement projects relative to their PPO plans, or to have their PPO plans meet minimum performance levels. M+C organizations offering PPO plans must still report on standard measures, however, and continue to comply with the QAPI requirements that apply to all plans, such as those relating to health information and program review. We are revising §422.152 to implement these changes.

Section 520(a)(3) of the BBRA defined a PPO plan as an M+C plan that (1) has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan; (2) provides for reimbursement for all covered benefits regardless of whether such benefits are provided within such network of providers; and (3) is offered by an organization that is not licensed or organized

under State law as a health maintenance organization. This definition is being added to the regulation at §422.4.

Comment: A few commenters addressed the costs associated with collecting and reporting QAPI data. They argued that the data required will add significant administrative costs to M+C organization operations, with two commenters contending that most of the patient encounter data required for quality improvement projects go beyond the claims data currently collected and processed by organizations and Medicare fiscal intermediaries. Another commenter suggested that because the data collection and reporting costs will be so significant, we should make decisions as to what information to require only after much deliberation. One commenter expressed concern that M+C organizations will pass along the costs of data collection and reporting to hospitals.

Response: While not all M+C organizations are accredited, the majority are either seeking or have already been granted accreditation by national bodies such as the National Committee for Quality Assurance (NCQA). For those organizations in particular, the collection and reporting of standard measures does not constitute a new activity as it is a condition of the accreditation process. In addition, many managed care organizations have been voluntarily conducting a variety of quality improvement projects over the years, although they may not have routinely reported on standard measures. Again, for

these organizations, the process of identifying quality of care concerns, selecting a patient population for study, implementing an intervention and collecting data on the outcomes of that intervention are not at all new. The quality improvement process under the M+C program is essentially comparable to current industry practice, with the slight addition of the requirement to report on specific types of indicators relevant to the condition in question. For these reasons, we do not believe that the data collection and reporting requirements established under the M+C regulations will impose unreasonable costs, and we believe that a great deal of deliberation has already gone into the establishment of these requirements (for example, the collection and reporting of HEDIS measures) at this time.

With respect to the issue of whether hospitals will be asked to bear costs associated with data collection, we do not expect these costs to be unreasonable, and we note that they are voluntarily assumed when the hospital decides to participate in the M+C organization's network.

Comment: A few commenters contended that the costs of implementing their QAPI programs would be excessive.

Response: We have given M+C organizations significant latitude in terms of designing their performance improvement projects, so that they can choose efforts that are relevant to their enrollees and that involve cost effective interventions To

further reduce administrative and financial burden, M+C organizations may collaborate with entities such as the Peer Review Organizations (PROs) on their performance improvement projects.

Comment: Two commenters addressed the collection and reporting of HEDIS measures. These commenters were concerned that the HEDIS measures do not, in their view, adequately address the health issues of older adults in Medicare, and they do not track the experiences of people with chronic and disabling conditions.

Response: M+C organizations are required to report HEDIS measures for the purposes of §§422.152(c)(1) and (e)(1). Currently, the HEDIS measures offer the most comprehensive view of managed care performance available. We have been working with the Geriatric Measurement Advisory Panel to develop additional measures for people with chronic and disabling conditions. It is important to recognize that HEDIS is an evolving instrument, and as valid measures of other aspects of care are developed, they will be incorporated. For example, HEDIS 1999 added measures for cholesterol management after acute cardiovascular events, and HEDIS 2000 has added a measure to assess whether blood pressure was controlled among people with diagnosed hypertension. Additionally, Medicare will be requiring six measures for people with diabetes. Additions such as these, plus others that will

be added as valid measures are developed, should address the commenters' concerns.

Comment: Two commenters suggested that we add other areas for standard measures in §422.152(e)(1) for M+C PFFS and non-network MSA plans. These commenters believe that the information collected for these types of plans should be as consistent as possible with that collected for other types of M+C plans to allow for comparison among them. The commenters recommended that if certain types of data are unavailable for non-network M+C MSAs and M+C PFFS plans, a statement should be made available to beneficiaries explaining the lack of information.

Response: We agree with commenters that for purposes of plan comparison, reporting on standard measures should be as consistent across plan types as possible. Therefore, we are revising §422.152(e) to specify that the standard measures on which reporting will be required for M+C PFFS plans, non-network MSA plans and now PPO plans will relate to the same areas to which the measures required for M+C coordinated care plans (other than the PPO plans) and network M+C MSA plans relate. As stated in the preamble to the interim final rule, no M+C organization will be required to report information to which it does not reasonably have access under a plan. Where data on particular measures are not reasonably available with respect to a given plan, organizations will be allowed to report "not available."

Comment: A number of commenters addressed the form and content of the required standard measures. One commenter asked that we develop core measures not just at the M+C plan level, but also at the provider and facility level. Another commenter asked that we develop core measures for high-risk, low-incidence conditions. Another commenter asked that we develop measures for all persons with disabilities under age 65 that are comparable to the senior health status data that are being collected for a sample of Medicare beneficiaries over 65 in Medicare managed care plans as part of HEDIS 3.0.

Response: Each of these suggestions has merit; however, we are taking an incremental approach to implementation with respect to the QAPI activities under the M+C program that includes working with private purchasers to expand the set of measures. We believe it is important to give M+C organizations time to adjust to the current standard measures before imposing further requirements. Our experience with the standard measures in place now will also be helpful in deciding whether additional measures are appropriate, and if so, which measures would be most effective.

Comment: Certain commenters asked that the standard measures we require be predictive of outcomes, and be established utilizing evidence-based medical research. One commenter asked that we establish a "data dictionary" that will give M+C

organizations detailed and clear definitions of the required measures. Another commenter cautioned that the development of another set of core measures for M+C organizations will result in unnecessary duplication and lead to confusion if the measures are defined differently by accreditation organizations and by HCFA.

Response: As mentioned earlier, M+C organizations are required to report HEDIS data. The HEDIS measures are predictive of outcomes, are well defined, and are well established in the private sector. Our requirements may change in future years as the HEDIS instrument evolves and as other measurement instruments are developed.

Comment: One commenter asked what role, if any, JCAHO's ORYX performance indicators will have in meeting our data reporting requirements, and whether there would be duplication. One commenter asked that we consider the OASIS data set and OBQI system for home care (and eventually PACE) to be reasonable alternatives to HEDIS for managed long-term care plans.

Response: Again, our goals with respect to data management are to minimize burden and maximize effectiveness. We are working collaboratively with accrediting organizations like the JCAHO, with these goals in mind. The ORYX indicators are still in the developmental stage and, furthermore, since they focus specifically on hospitals, they cannot be used to measure much of the performance of managed care organizations. All home health

agencies serving Medicare beneficiaries, whether in managed care or traditional Medicare, are required to provide information through OASIS. In general, we are not requiring managed long-term care plans to provide HEDIS information, with the exception of several demonstration sites. However, reporting requirements for long-term care entities may change in the future.

Comment: A few commenters addressed our intention to consider historical plan and original Medicare performance data and trends when establishing minimum performance levels. One asked for clarification as to the standards we will use. Two objected to basing minimum performance levels on historical performance data and trends, explaining that many Medicare program requirements, including those related to access to services, emergency services and due process, are not ideal targets, but rather legal requirements under Federal law. The commenters were concerned that looking to historical performance might result in establishing a minimum performance level that is less than what the law requires.

Response: We agree with commenters that it would not be appropriate to establish minimum performance levels for aspects of care or service for which required levels of performance have already been dictated by regulation or statute. However, there are many measures of care, such as mammography or immunization

rates, for which no mandated minimum exists. In these areas, it is useful to know what historical performance has been, because while we are interested in establishing minimum performance levels that motivate improvement, we want those levels to be achievable. At this time, the process for establishing minimum performance levels has not been finalized, but we expect that we will set the minimum at a percentile of previous performance, and revise the minimum year by year as overall performance rises.

Comment: A number of commenters objected to our intention to establish minimum performance levels. One commenter said that it would be inconsistent with our statement in the preamble to the interim final rule that we would not adopt a "one size fits all" approach to performance measurement. Another commenter, although not opposed to minimum performance levels, asked that we take into consideration variation in the model of delivery, such as network-model or group-model, when establishing the levels.

Response: We believe that it is feasible and in the best interest of Medicare beneficiaries to require that the quality of care provided by M+C organizations offering network plans meet minimum standards. This is an additional protection above making performance information available to beneficiaries for the purpose of plan selection. We believe that there would be a de facto requirement that organizations achieve minimum performance levels, even if there were no explicit requirement in the

regulation. That is, even if the regulation required only that organizations report their performance on standard measures, we would still judge their performance by comparing it with some benchmark for the purpose of determining whether to take remedial action or continue contracting with the organization, which would have the same effect as applying a minimum performance level. We see no reason not to recognize this implicit requirement in the regulation.

As we stated in the preamble to the interim final rule, we are sensitive to the different structures of plans. We will consider the impact plan structure has upon the ability of an M+C organization to affect provider behavior. We will consider these issues when making our decisions regarding the standard measures for which it is appropriate to establish minimum levels of performance.

Comment: Two commenters addressed the possibility that some of the minimum performance levels HCFA establishes will be regional instead of national. One commenter objected to establishing non-national performance levels. The other supported the idea of establishing minimum performance levels with consideration for regional area variation.

Response: Because it is our intention to establish minimum performance levels that are meaningful as well as achievable, we must consider regional variation where it exists. It is our

ultimate goal to have national minimum performance levels, but it may be necessary to move towards this goal incrementally by first establishing regional performance levels.

Comment: One commenter asked how we can require that M+C organizations meet minimum performance levels 1 year after the levels are established, if we recognize a 3-year cycle as the standard for performance improvement.

Response: The purpose of performance improvement projects is not to bring plan performance up to minimum performance levels, but rather to move it closer to national benchmarks. In most cases, we believe that plan performance would already surpass the "minimum performance levels" that we are now in the process of developing. An immediate intervention and not a lengthy performance improvement project would probably be called for if a plan offered by an M+C organization failed to meet a minimum performance level.

Comment: One commenter asked that we establish some minimum performance levels related to the care of persons with disabilities.

Response: As noted above, we are still in the early stages of identifying the measures for which minimum performance levels will be established. When we do, we will consider the commenter's suggestion.

Comment: A number of commenters objected to the possibility that we will nonrenew an organization's contract on the basis of its failure to meet minimum performance levels. Two of these commenters complained that any organization might fall short of a specific numerical standard because of random events beyond its control. As an alternative to nonrenewal, one commenter asked that we impose intermediate sanctions. Another asked that we not impose sanctions at all if an organization is making a good faith effort to meet the requirements. Some commenters suggested that we work with organizations to improve their performance in lieu of nonrenewal. In particular, one commenter recommended that we require organizations to participate in PRO-sponsored improvement projects when minimum performance levels are not met.

Response: As a value-based purchaser, HCFA has a responsibility to implement requirements that promote accountability on the part of M+C organizations. Although we have the authority to nonrenew an organization's contract for failure to meet quality assurance requirements, we have stated that in most instances we will first offer technical assistance and/or require corrective action plans. Intermediate sanctions are also within HCFA's prerogative.

Comment: One commenter asked that we reward an organization that shows demonstrable improvement in the health status of beneficiaries by giving it a bonus payment such as a percentage

of its capitation rate. The commenter contended that a bonus payment is necessary to ensure that organizations are equitably reimbursed, since under a risk-adjusted ACR, organizations will receive lower payments for healthy enrollees.

Response: It is appropriate that an M+C organization receive lower payments for healthy enrollees because the cost of caring for them is proportionately lower. Because an organization that successfully completes a performance improvement project will have reduced the incidence of negative outcomes and the expenses associated with them, any reduction in Medicare payment as the result of risk adjustment should not adversely affect the organization's profitability. Indeed, the successful completion of performance improvement projects should bolster an organization's business. The information that an organization has successfully completed performance improvement projects will be shared with potential enrollees, and should help its market position.

Comment: One commenter asked that we establish public recognition awards at the state and national level for innovative and successful organization performance improvement projects.

Response: Although there has been much discussion around the issue of establishing performance incentives, we currently have no plans to develop an awards program for M+C organizations. However, they may wish to consider promoting their excellent

performance themselves through the media and their marketing materials.

Comment: One commenter requested that we specify the nature and form of the documentation and data that organizations must make available to demonstrate compliance.

Response: With respect to monitoring compliance, we have completed the design of a revised M+C interim monitoring tool that follows the structure of both the M+C regulations and the Quality Improvement System for Managed Care (QISMC) Interim Standards and Guidelines (which provide interpretive guidance for both subpart D standards as well as standards relating to the delivery of health care and enrollee services). The monitoring tool specifies the documentation and data that we will look for in our compliance monitoring.

Comment: Many commenters emphasized the importance of collaboration between the managed care industry and HCFA as implementation of the regulation proceeds. One commenter recommended that we establish a formal advisory counsel composed of representatives of industry associations. Other commenters urged that we consult with physicians and accreditation organizations in selecting standard measures and setting minimum performance levels.

Response: Since we began developing QISMC 4 years ago, we have been engaged in an ongoing dialogue with representatives of

the managed care industry, advocacy groups, various health care providers, and state regulatory bodies to ensure broad involvement in the document development process. We recognize the value of this type of collaborative exchange and intend to continue this activity.

Comment: A number of commenters asked that we coordinate our quality improvement efforts with those of the private sector, particularly NCQA. One commenter was concerned that we are establishing an independent system of quality improvement requirements rather than building upon the collaborative public-private efforts that we have participated in, such as HEDIS.

Response: The QAPI requirements established in the regulation build upon a number of the public-private efforts mentioned by commenters. For instance, as noted above, the standard measures on which M+C organizations now are required to report to comply with §422.152 (c)(1) and (e)(1) are the HEDIS measures; we have been collaborating with private sector group purchasers since 1994 to develop these measures, and we recognized the value of incorporating them into our QAPI strategy.

Comment: One commenter questioned HCFA's authority to require that performance improvement projects achieve "significant" improvement, pointing out that the statute requires only that M+C organizations "take action" to improve quality.

Another commenter questioned our authority to impose as much structure on performance improvement projects as we have, asserting that by requiring that projects focus on specified areas of clinical and nonclinical services, and directing M+C organizations to undertake specific projects among the required areas, we have exceeded our statutory mandate.

Response: We believe that our responsibility as a value-based purchaser and duty as a trustee of Medicare funds includes requiring that M+C organizations provide high quality services, and the statute recognizes this responsibility. For instance, section 1852(e)(2)(A)(vi) of the Act requires that M+C organizations "provide the Secretary with such access to information collected as may be appropriate to monitor and *ensure the quality of care provided under this part*" (emphasis added). Requiring that M+C organizations conduct projects that achieve improvement that is significant and sustained over time is one way for us to meet our obligation under the statute. We also believe that the language quoted by the commenter, requiring that M+C organizations "take action" to improve quality can be reasonably interpreted to require that improvement actually occur. A requirement to "take action" to improve quality clearly suggests that the M+C organization have an objective in mind in doing so. We believe that a significant improvement is a

reasonable and logical objective for "action" to improve quality. While the structure imposed in the interim final rule is flexible, and grants M+C organizations broad discretion in many areas in designing their QAPI programs, we believe that some structure is necessary in order to ensure that the projects will be meaningful for Medicare enrollees. We believe that the M+C quality assurance requirements represent a reasonable interpretation of requirements in section 1852(e), and a reasonable exercise of our broad authority under section 1856(b)(1) to establish M+C standards by regulation.

Comment: Two commenters addressed the issue of the number of performance improvement projects M+C organizations are required to perform. One commenter explained that it is difficult to conduct valid and reliable performance improvement projects with a small number of participants, and asked that the number of required performance improvement projects be proportionate to the size of the plan. The second commenter asked that we limit the number of required performance improvement projects to one new project per year, and limit the number of projects required to be underway at any one time to four.

Response: QISMC requires that M+C organizations initiate two performance improvement projects a year. Given that projects are allowed 3 years in which to achieve significant improvement, once

QISMC is fully implemented an organization will not need to have more than six projects underway at any one time: two in the initiation stage, two in the intervention stage, and two in the completion stage. We believe this is a reasonable burden for both large and small plans. Smaller plans are not at a disadvantage because organizations are not required to show statistically significant improvement on every topic affecting a small population. Statistical significance is only required in instances when an organization chooses to sample its population. For small populations, an organization has a strong incentive to measure the results of its project on the entire affected population, because, when the organization's project targets the entire affected population, only a 10 percent reduction in the "performance gap" is required, not statistical significance. For example, if an organization chose to study a condition that affected only 100 enrollees, and its current performance was 50 percent, to achieve a 10 percent reduction in the performance gap it would have to demonstrate that it improved the care to five enrollees. If the organization measured the results of its project on a sample of the population, it would have to show improvement for many more enrollees to achieve statistical significance.

We are aware that a number of technical issues relating to improvement project design remain to be resolved. For instance,

we must decide what to do when a project population is so small that measurement of the results of the project is not meaningful or what to do if the baseline performance is so high that the sample size required for statistical significance is very large. We intend to resolve these issues in an updated version of QISMC.

Comment: One commenter pointed out that a significant period of time will be required following the intervention before improvements are observed at the population level, and the commenter was concerned that there appears to be no allowance for this time period.

Response: QISMC allows for such a time period. As mentioned earlier, QISMC does not require a performance improvement project to achieve significant improvement until the end of its third year. Experience has shown that there are many opportunities for an intervention to yield results within three years. QISMC makes an even more generous allowance for more complicated projects.

Comment: Many commenters addressed the requirement that performance improvement projects achieve significant improvement. The majority of these commenters opposed the 10 percent standard for reduction in the performance gap. As discussed above, this standard (which is specified in QISMC) requires that the organization reduce by at least 10 percent the percentage of cases in which the quality indicator that measures its

performance in the project's focus area is failed. Several of these commenters complained that the standard is not realistic. One commenter explained that in many data situations, administrative claims may not be complete or be reliable to allow for a meaningful evaluation. Other commenters offered other examples of impediments to achieving significant improvement, including regional variation of utilization and imperfect provider and enrollee compliance. One commenter asked us to recognize that enrollee lifestyle choices, diet, and compliance with medical treatment will impact upon an organization's ability to achieve significant improvement in health status. Another commenter asked that we recognize that it is the provider who actually has control of the care process. For these reasons, these commenters asked that we not hold organizations responsible for achieving significant improvement, but for initiating activities that, if followed by enrollees and providers, are likely to improve the health status of enrollees.

Two other commenters suggested that we take a different approach. They recommended that in lieu of requiring a 10 percent reduction in the performance gap, we follow NCQA's approach and require that managed care organizations provide meaningful evidence that they are making improvements in clinical care and service. One of these commenters suggested that to define "meaningful," we consider whether the improvement resulted

in a better outcome for the enrolled population, whether it is attributable to the organization's actions, and whether it affects high-volume, high-risk, and/or high-cost conditions or services. The commenter added that this would be more effective in encouraging complex or innovative projects that have a high risk of failure but that offer significant potential, a comment that was echoed by other commenters who were concerned that a rigid numerical significant improvement standard would encourage organizations to pursue performance goals that are easily attainable.

A third alternative to the 10 percent standard was submitted by a commenter concerned that certain characteristics of the Medicare population will complicate the achievement of significant improvement. This commenter pointed out that the elderly population is at a higher risk of illness and disease, and that a greater percentage of Medicare beneficiaries have multiple disabilities and comorbidities, which results in greater instability in their health status. This commenter recommended that we require only that organizations establish measurable goals for their interventions, and that we evaluate organizations on their ability to demonstrate the strength of their interventions and performance gains over time. Further support of this approach was offered by an additional commenter who was concerned that the 10 percent standard would encourage risk

selection and discourage the enrollment of sicker beneficiaries with more complex health issues.

Response: We chose to make a 10 percent reduction in the performance gap the standard because we believe it is necessary to have an objective standard to assess whether an organization has achieved significant improvement in health care quality, and because we have observed much higher percentage increases in performance than 10 percent. Therefore, 10 percent is a reasonable benchmark to use based on our observation of past organizational performance in improving health care quality. Nationally recognized standards that do not incorporate objective standards for determining if quality improvement has occurred have been criticized as being subjective and lacking in reliability and validity. We have learned from the lessons of such standards, and based on the strong evidence from the Medicare and Medicaid programs, have elected to implement a standard that is consistent with our knowledge of quality improvement in both the Medicare and Medicaid programs.

The 10 percent improvement standard is the best way we have at present to ensure that projects are meaningful, and that they translate into positive changes in enrollees' lives. In the long run, in order to mitigate the incentive to choose trivial projects, we will attempt to devise a way to measure and report the relative contribution of each performance improvement

project, taking into account such factors as the number of enrollees affected by the improvement and the impact the improvement actually has upon enrollee health and satisfaction. Such a system is years away, but we have taken a first step towards it by starting to develop a common vocabulary for performance improvement projects.

As for the comment that requiring a 10 percent reduction in the performance gap will encourage risk selection, we believe that there exist numerous opportunities for M+C organizations to improve performance on measures relating to the care of sicker enrollees with complex health care needs. In fact, we believe the improvement potential associated with the care of sicker enrollees exceeds that associated with the care of healthier enrollees. In addition, the introduction of risk-adjusted payments to M+C organizations should further discourage risk selection.

Comment: One commenter was concerned that allowing an organization to set its own performance goals would be a disincentive to undertaking any project that might "lower its status" with us or with enrollees.

Response: We believe the commenter is referencing the QISMC standard that addresses projects in which data are collected on the entire population to be studied (that is, in which a census is involved). QISMC specifies that, in the case of a project

developed by the organization itself, significant improvement is demonstrated by achieving a benchmark level of performance that is defined in advance by the organization. However, the standard goes on to say that the organization's benchmark must reduce the opportunity for improvement by at least 10 percent, which is the same standard for HCFA specified projects. So, the commenter's concern is unfounded because the objective nature of the benchmark ensures an acceptable level of effort on the part of the organization.

Comment: One commenter noted that when multiple interventions are employed, they all would have the potential to bring about improvements in outcomes. The commenter asked how we will determine which intervention was responsible for the observed change.

Response: It is only necessary that an M+C organization show that its improvement was the result of its own actions and not chance. It is not necessary to determine to which of its interventions the improvement should be attributed, although we expect that the M+C organization will want to do so for its own management purposes.

Comment: A number of commenters addressed the issue of required participation in national or statewide performance improvement projects. Half of the commenters supported the idea of such projects. One commenter asked that we consider the

identification and diagnosis of persons with Alzheimer's as a possible national performance improvement project, and another asked that we require organizations to participate in national improvement projects pertaining to persons with disabilities.

One of the commenters opposed to national or statewide performance improvement projects complained that mandated projects will detract from the flexibility organizations need to best care for their enrollees. This commenter pointed out that many organizations have already conducted projects addressing flu and pneumonia; consequently, it would be a poor use of resources for them to be required to conduct another such project. Another opponent argued that national or statewide performance improvement projects may prove to be inconsistent with local market considerations.

Response: In response to these concerns, we included in OPL 98-72 a statement that an M+C organization is not required to participate in the HCFA-sponsored national diabetes project but may, at its discretion, conduct another diabetes-focused project that utilizes the Diabetes Quality Improvement Program (DQIP) indicators, and meets the project requirements as outlined in QISMC Domain 1. For their second performance improvement project, M+C organizations were free to select a topic and focus area of their choice.

With respect to the concern that organizations may have already conducted projects addressing influenza and pneumonia, which have been selected as the national project topics for 2000, there are many aspects to the care and prevention of these diseases that organizations may not have fully addressed in previous projects that would lend themselves very well to further projects.

At this point, we have not selected national project topics beyond year 2000, but we will consider the care of enrollees with Alzheimer's and with disabilities when making future selections.

Comment: One commenter asked us how we will decide who must participate in national or statewide performance improvement projects.

Response: It is a contracting requirement for all M+C organizations offering coordinated care plans that they conduct a project addressing a topic that we have determined represents a national health care priority. At this time, although we have the authority to specify State-specific topics, we have not done so.

Comment: One commenter advocated that we explicitly include requirements in the regulation for organization participation in PRO-sponsored activities.

Response: There is no requirement that organizations participate in PRO-sponsored activities: there is only the

requirement, as stated in QISMC, that one of the two performance improvement projects that an organization initiates per year relate to a topic and involve quality indicators chosen by us. The PRO is required to provide technical assistance on the national project (and on all other projects) if an organization requests it, but organizations are not required to work with the PROs on their projects. However, we expect that many organizations will choose to work with the PROs, because the PROs can provide clinical and biostatistical expertise; assistance in the design and conduct of projects; advice on sampling, data collection and analysis; and, review and analysis of project findings and interventions.

Comment: A few commenters opposed allowing organizations to select the topics of their performance improvement projects from within the specified clinical and nonclinical areas. One commenter was concerned that organizations will choose the disease with which they are most familiar, thereby neglecting low- incidence diseases. Two other commenters were concerned that organizations will avoid undertaking projects in areas that highlight poor performance or that relate to discrete, but vulnerable, cohorts of patients, such as those with disabilities or rare conditions. These commenters recommended that as alternatives to allowing organizations to select their own performance improvement project topics, we standardize the topics

across all organizations; we standardize the topics across all organizations within a given service area, selecting the topics on the basis of the morbidity and mortality measures for seniors in the service area; or, we select the topics for each individual organization on the basis of needs identified through an annual onsite audit.

Response: We believe it is essential that M+C organizations be allowed to target at least some of their performance improvement activities to those areas they determine would be of most benefit to their enrollees. Balanced against this opportunity is the obligation to address areas that we consider to be of universal importance to the Medicare population. Between organization-specific projects and national projects, we expect that all significant improvement opportunities can be addressed. If upon review we find that an organization's performance in a particular aspect of care or service is poor and the organization has repeatedly failed to initiate action to improve it, we have the authority to direct that the organization do so.

Comment: Two commenters asked that we expand the required clinical focus areas. One asked that we include high-risk, low-incidence conditions and populations, and the other asked that we include laboratory and other diagnostic services.

Response: High-risk, low-incidence conditions are subsumed within the high-risk focus area. Although issues selected for study generally should affect a significant portion of the organization's Medicare enrollees (or a specified subpopulation of enrollees), organizations should target infrequent conditions or services if data indicate they warrant study. As for laboratory and other diagnostic services, they could fall under a number of the current focus areas. Therefore, we do not find it necessary to add to the current list of focus areas.

Comment: One commenter asked how "high-volume services" and "high-risk services" are defined.

Response: We did not provide a definition of "high-volume" or "high-risk" services for several reasons. First, it was our intention to allow organizations discretion in developing their own definitions and criteria, consistent with the needs of their organizations. For the most part, both terms have commonly understood meanings, and therefore, we did not think they required explanations.

Since M+C organizations will be monitored on whether they conduct QAPI projects addressing these focus areas, and to respond to the request for further information, we suggest that organizations consult the QISMC Interim Standards and Guidelines (specifically, Standards 1.3.4.5 and 1.3.4.6) for further guidance as to our expectations. In selecting a quality

improvement project focusing on high-risk or high-volume services, we note that the focus does not necessarily have to be on a clinical condition per se, but on a service and how it may be improved. In HEDIS 99, Volume 2, Technical Specifications, there are several clinical conditions for which suggested indicators are provided in assessing "High-Occurrence/High-Cost" DRGs. Congestive heart failure, angina pectoris, chronic obstructive pulmonary disease and other conditions which place the enrollee at risk of increased morbidity or mortality would certainly constitute appropriate conditions under the "high-risk" category. An organization may assess experiences of care received from specialized centers inside or outside of its network, such as burn centers, transplant centers, or cardiac surgery centers. With respect to "high-volume" services, an M+C organization may target quality improvement in a frequently performed surgical procedure, or across different surgical or invasive procedures.

Comment: One commenter asked how "clinical area" is defined. The commenter asked whether it is a clinical condition, such as diabetes, or, an opportunity within a clinical condition, such as the number of glycohemoglobin blood tests performed for diabetic enrollees.

Response: The answer is that it can be either. Standard 1.3.4 of the QISMC Interim Standards and Guidelines provides

additional detail regarding the specific focus areas. It should be noted that in choosing the areas, we avoided a disease-specific focus, opting instead to define them in a broad sense and therefore allow M+C organizations maximum discretion in determining where their specific project might best fit. For example, performance of dilated eye exams in the diagnosis and treatment of diabetic retinopathy might best be placed under the clinical focus area of Secondary Prevention of a chronic condition (Standard 1.3.4.2), as it serves to identify and potentially control a diabetes-related condition.

Comment: One commenter recommended that the clinical area of "continuity and coordination of care" include an evaluation of whether the appropriate mix of services is being furnished, and of whether there is adequate access to specialty care.

Response: These are aspects of continuity and coordination of care that organizations may choose to select as project topics. However, we will not require these as topics because such specificity might serve to unduly restrict an organization in its efforts to identify those aspects of care and service most in need of a formal performance improvement project. General requirements and concepts relating to continuity of care and access to services are found at §422.112.

Comment: Two commenters addressed the need to coordinate performance improvement projects. The first commenter asked that

in areas where there are multiple M+C organizations, we require that organizations coordinate their selection of project topics so as to minimize the data gathering and reporting burden that will be imposed on hospitals. The second commenter asked that we allow M+C organizations serving in more than one region to partner in collaborative projects, perhaps under the aegis of a national organization such as the Blue Cross Blue Shield Association. This commenter also asked that we permit collaborative projects through the Agency for Health Care Policy and Research (now known as the Agency for Healthcare Research and Quality) or professional organizations/societies.

Response: We agree with these commenters. We have consistently stated that we encourage M+C organizations to collaborate across plans, with other organizations, and within their States and regions to promote reduction of administrative burden and to enhance the general applicability of study findings. Certainly, the PROs may serve in a convener/collaborator role with respect to promoting such activity. To further this effort, we co-sponsored a National Diabetes Conference in conjunction with the American Association of Health Plans and the American Diabetes Association to provide additional guidance and materials which may be used uniformly by M+C organizations in the conduct of their diabetes performance

improvement projects. We expect other ad hoc collaborations to occur in the future.

Comment: One commenter asked that we encourage M+C organizations to work with their contracted providers, as well as other health care professionals and associations, in developing their performance improvement projects.

Response: As indicated in the previous response, we recognize the importance of collaboration. To that end, QISMC requires that an organization allow its providers (and enrollees) an adequate opportunity to provide input regarding the selection and prioritization of performance improvement projects.

Comment: Two commenters addressed the requirements relating to health information. One commenter claimed that without uniform collection methods, it is unreasonable to require organizations to ensure that the information they receive from providers of services is reliable and complete. This commenter believes that some organizations, especially those offering non-network M+C MSA plans and M+C PFFS plans, will be unable to meet this requirement. The other commenter asked that we clarify what level of organization oversight will be necessary for an organization to meet the requirement that it ensure the reliability and completeness of the information it receives from providers of services.

Response: To promote continuous quality improvement, it is essential that collection and management of meaningful statistical information be seen as means to that end. Statistically valid data that assist in explaining patterns of care and in justifying variations in care are as valuable as data that identify problems in the provision of care. Without good data, we cannot make scientifically defensible or financially meaningful health care decisions. Therefore, collection of appropriate and accurate data is both good science and good business. To the extent that a particular M+C organization currently is unable to meet these requirements, we believe that the answer is not to change the requirements, but for the organization to make the changes necessary to be able to meet these requirements.

As for oversight of the health information system, the organization is ultimately responsible for determining at what level within its structure there will be oversight which ensures the reliability and completeness of information received from providers.

Comment: One commenter suggested that we require that organizations, in processing requests for initial or continued authorization of services, follow written policies and procedures that reflect scientifically sound and evidence-based medical guidelines, rather than reflect current standards of medical

practice. The commenter contended that not all current standards reflect the best medical practices.

Response: Historically, current standards of medical practice have been the benchmark for care provided by managed care organizations. The purpose of using these standards has been to ensure that the quality of care delivered through managed care organizations was comparable to, or better than, that provided by fee-for-service entities. During the last decade, advances in quality measurement and the development of practice guidelines and improved mechanisms for assessing utilization management have been adopted as standard practice in many organizations.

We agree with the commenter that in processing requests for authorization of services, the organization should follow policies and procedures that are based on scientifically sound and evidence-based guidelines. Nevertheless, we recognize that in instances where such guidelines do not exist, individuals making authorization determinations may need to refer to current standards of medical practice. In those cases, an M+C organization must have in place written policies and procedures to ensure that all coverage decisions are designed to provide care in the safest, most beneficial and cost-effective fashion.

Comment: One commenter asked that we require organizations offering M+C PFFS and non-network MSA plans to use written

protocols for utilization review, and to provide their utilization review findings to enrollees and providers at least annually.

Response: Section 1852(e)(2) of the Act does not require that M+C PFFS and non-network MSA plans (and under the BBRA, PPO plans) establish written protocols for utilization review. To the contrary, section 1852(e)(2)(B)(ii) imposes requirements "insofar as" an organization provides for such protocols, clearly contemplating that some M+C organizations may choose to do so, and some may not. Thus, we do not believe that such a requirement would be consistent with statutory intent.

Comment: Four commenters were concerned about the lack of an explicit requirement that organizations take immediate remedial action when individual quality problems are found. Two commenters explained that performance measurement and performance improvement projects result in the collection of data that can be used to establish baselines and track performance over time, but neither serves as a mechanism for ensuring that real problems experienced by current enrollees are systematically identified and corrected. These commenters recommended that we require that organizations "take appropriate remedial action whenever inappropriate or substandard services have been provided or services that ought to have been furnished have not been provided."

Response: Clearly, an essential component of any effective "ongoing quality assurance program" as required under section 1852(e) of the Act is the correction of identified problems. QISMC already requires that an organization correct significant systemic problems that come to its attention through internal surveillance, complaints or other mechanisms. As the commenters suggested, we are adding a modified version of this requirement under new §422.152(f)(3) to require correction of all identified problems, because it is our intention that an organization take appropriate remedial action whenever a problem comes to its attention. Although §422.152 generally focuses on systemic improvement, we believe it is appropriate to make our intention explicit. In monitoring this requirement, HCFA reviewers will operate by a "rule of reasonableness," taking into consideration factors including but not limited to the severity and prevalence of the complaints and the level of effort demonstrated by the organization in seeking to resolve the matter.

Comment: Many commenters addressed the relationship between QISMC and the M+C regulations. Two commenters asserted that it was premature to model the regulation on the QISMC requirements, arguing that the QISMC requirements should be tested and evaluated before being applied to M+C organizations. These commenters asked that we scale back the quality assurance requirements until after they have been tested and evaluated, and

if appropriate, restore them to the regulation using the normal notice and comment process. Two other commenters also recommended deleting the QAPI requirements of QISMC from the final rule, explaining that there are areas within QISMC that should be refined before they are implemented, such as the number and kinds of performance improvement projects that will be required.

Response: As we mentioned earlier, we have developed a cross-walk between the QISMC requirements and the NCQA accreditation requirements, which are currently considered the industry standard. For the most part, QISMC requirements are either identical to or consistent with NCQA requirements. Therefore, we are confident that our expectations have not outpaced the state of the art. Also, the HEDIS measures on which M+C organizations must report have already been fully tested and adopted by the managed care industry.

Finally, in response to concerns raised by managed care organizations regarding the potential burden imposed by the QISMC performance improvement project requirements, we significantly scaled back the number of required projects per year from nine required projects to only two per year. To assist M+C organizations further in this effort, we are currently developing model performance improvement projects and other implementation tools.

Comment: Two commenters addressed the time frame for QAPI program implementation. The first commenter recommended that the regulation reflect the transition policy found in the QISMC document, which allows organizations a period of time in which to build and refine their quality assessment infrastructure before their quality improvement projects will be expected to achieve significant improvement. The second commenter echoed the need for a long implementation time frame.

Response: Implementation policy is more appropriately handled through the issuance of operational policy letters and program manuals than through regulation. In addition, we have stated publicly that we will "phase-in" both implementation and enforcement of these requirements, in recognition of the fact that many organizations are still navigating the performance improvement learning curve.

Comment: A few commenters objected to the statement in the preamble to the interim final rule that we would not make public the results of an organization's performance improvement projects. One commenter complained that such a policy would be contradictory to our commitment to informed consumer choice. Another commenter challenged our rationale for withholding results, which was that releasing them might compromise enrollee confidentiality as they might involve enrollee-specific information. This commenter suggested that we redact enrollee-

specific information, or direct organizations to report information in ways that protect enrollee identities. Another commenter also supported the notion of releasing pertinent, non-confidential information about organization quality gleaned from performance improvement projects.

One commenter praised the policy we put forth in the preamble, explaining that providing the results of performance improvement projects to Medicare beneficiaries could undermine the legal confidentiality of peer review activities and could make such information reported outside the organization discoverable in legal proceedings. Another commenter also expressed support for our disclosure policy, noting that performance improvement requirements are new and that a non-punitive atmosphere is most conducive to improvement. However, this commenter recommended that we reexamine our disclosure policy in the future, and make it our goal to provide public access to performance information that will not violate patient confidentiality.

Response: To promote collaboration, we believe that it is important where possible to share development of best practices and interventions that work. In addition, to provide the necessary information to assist enrollee decision-making as they choose among various health plans, it is essential that we inform the public generally as to whether an M+C organization has met

its responsibility to achieve demonstrable improvement. M+C organizations are free to release the specific results of their performance improvement projects, and we encourage this, but we do not believe such release should be mandatory. We are concerned that M+C organizations might be reluctant to undertake projects addressing their areas of poorest performance, if that means that their poor performance will be highlighted. The natural progression of performance improvement projects will be to generate additional measures for inclusion in the HEDIS data set. At that point all organizations will be required to submit this information for public disclosure.

We note that we do make a substantial amount of information available to the public for research purposes, such as the HEDIS public use file on our website; moreover, there is nothing to preclude researchers from attempting to obtain information directly from the M+C organizations themselves as long as enrollee confidentiality is protected.

Comment: Certain commenters asked that we require M+C organizations to report their performance on standard measures and the results of their performance improvement projects to entities other than HCFA. One commenter asked that we require that organizations report their performance on standard measures to their designated external review entity. The commenter explained that this information would help optimize the

effectiveness and timeliness of interventions by the PROs, which as the external review entities will be assisting organizations in meeting their QAPI requirements. Another commenter recommended that organizations be required to make information available to their State, in that the organization is licensed under State law. A third commenter asked that organizations be required to share the results of their performance improvement projects with the Agency for Health Care Policy and Research (now known as the Agency for Healthcare Research and Quality).

Response: We agree that it is essential that the PRO, in its role as independent quality review and improvement organization, have access to performance data, but it is preferable that the data not go directly from the M+C organization to the review organization (or State) for two reasons. First, the M+C organization's reporting burden would be doubled. Also, raw performance data are not useful to the review organization, State, or HCFA, which is why we have contracted with NCQA to analyze the data for us. M+C organizations will report the HEDIS measures to NCQA, and after its analysis, NCQA will report the measures to us. At this point, we will share summary data with the review organizations and States.

The same is true for the results of performance improvement projects. We again believe it preferable that performance improvement project data not go directly to the PRO. The data

will be reported either to HCFA or to the specialized quality review organizations with which we have contracted to evaluate the success of performance improvement projects (the M+C/QROs). HCFA or the M+C/QROs will then present and interpret the results for the PROs.

### 3. External Review (§422.154)

Section 422.154 implements section 1852(e)(3) of the Act. Section 1852(e)(3) requires, subject to certain exceptions, that each M+C organization, for each M+C plan it operates, have an agreement with an independent quality review and improvement organization approved by us to perform functions of the type described in part 466 of chapter 42, which establishes review responsibilities for utilization and quality control Peer Review Organizations (PROs). This general requirement appears in §422.154(a) of the interim final rule. The terms of the agreement are described in §422.154(b), and the exceptions to the general requirement are stated in §422.154(c).

Comment: One commenter expressed concern that organizations contracting with both Medicare and Medicaid would be burdened by dual external reviews.

Response: Sections 1932(c)(2)(B) and (C) of the Act specifically address this scenario. The first provision authorizes a State to exempt a Medicaid-contracting managed care organization (MCO) that is accredited by a private independent

entity, or that has a Medicare review conducted under section 1852(e)(3) of the Act, from Medicaid review activities conducted under section 1932(c)(2)(A) of the Act that would be duplicative of the accreditation process or the Medicare review activities. The second provision provides a State with the option to exempt entirely from the external review requirements under section 1932(c)(2)(A) a Medicaid MCO that is also an M+C organization, as long as that organization has had a Medicaid contract under section 1903(m) for at least 2 years during which the new BBA external quality review procedures are in effect. On December 1, 1999, we published a separate notice of proposed rulemaking setting forth our proposed interpretation of these provisions of section 1932(c)(2) of the Act (64 FR 31101).

Comment: A number of commenters asked that the regulation identify distinct review organization functions. One commenter recommended the following functions: population-based surveillance monitoring of access, quality and outcomes of care in M+C plans; auditing and validating the results of performance improvement projects; sponsoring national and statewide performance improvement projects; investigating quality complaints; conducting reconsiderations of hospital notices of non-coverage and conducting expedited appeals; and collaborating with consumer assistance organizations to better understand and use national and statewide performance improvement information

when counseling beneficiaries on plan selection. Another commenter asked that we define external review requirements in the regulation that align with the PRO contractual requirements delineated in the Sixth Scope of Work.

Response: As we explained in the preamble to the interim final rule, we have approved the PROs to serve as independent quality review and improvement organizations (review organizations) for the purpose of this section of the regulation. We believe that the functional specifics of review organization responsibility are more appropriately detailed in the PRO scope of work than in the regulation. As M+C organizations implement their QAPI programs, needs may become apparent that will suggest that the review approach of the PRO be refined. The scope of work process permits a more rapid response to changing circumstances than does the regulatory process, which we believe should be used only for purposes of making changes in substantive standards for review.

Comment: One commenter asked that we require review organizations to involve broad community interests, particularly representatives of the Medicare beneficiary and consumer communities, in policy making and review activities.

Response: Such a requirement already exists. As stated in the PRO manual, each PRO is obligated to have at least one consumer representative on its governing board, and that

representative must be a Medicare beneficiary. In addition, the Sixth Scope of Work requires each PRO to conduct beneficiary outreach and to maintain a Medicare hotline to facilitate communication with beneficiaries within its State.

Comment: One commenter addressed the external review waiver, supporting our decision to delay rulemaking on the waiver until we have experience with the implementation of the QAPI program.

Response: We appreciate the commenter's support of our decision.

Comment: A few commenters addressed our intention to exempt M+C organizations from external review activities that duplicate our monitoring activities. Two commenters argued that such a policy has no statutory basis and advocated its elimination. These commenters believe that this policy is inconsistent with the fact that HCFA, as Medicare purchaser and regulator, is ultimately responsible for monitoring and overseeing all quality assurance functions including the work of both review organizations and accreditation organizations. The commenters stated that our work, by definition, necessarily duplicates the work of review organizations, and therefore they were concerned that we would use the duplication as a pretense to design a PRO scope of work that is meaningless and insignificant. One commenter, although not opposed to exemption in principle, asked

that any exemption of external review activities be subject to the notice and comment process.

Response: Section 1852(e)(3)(B) of the Act mandates that the Secretary ensure that the external review activities under section 1852(e)(3)(A) of the Act "are not duplicative of review activities conducted as part of the accreditation process." The commenter is correct that HCFA has overall responsibility for monitoring and overseeing quality assurance functions. We believe that this extends to our review of areas addressed in the accreditation process. In this sense, we believe that our quality monitoring activities constitute a part of an overall "accreditation process" in that they are relevant to the continuing accreditation of M+C organizations. We also believe that Congress intended in section 1852(e)(3)(B) of the Act to require that we ensure that external review activities are not duplicative generally. Because there is little value and much additional burden in having the review organization repeat monitoring activity already conducted by HCFA, we are interpreting section 1852(e)(3)(B) of the Act broadly to extend to review activities that would be duplicative of our own monitoring activities. We believe that this interpretation of the intent of section 1852(e)(3)(B) of the Act, combined with our broad authority under section 1856(b)(1) of the Act to establish

M+C standards by regulation, supports our decision to ensure that external review activities are not duplicative of our own review.

With respect to the comment that our application of the "anti-duplication" policy in section 1852(e)(3)(B) of the Act be subjected to notice and comment, we believe that the process of determining whether review activities are duplicative in a given case represents "operational" implementation of the substantive standard set forth in the regulations. We believe it would be neither workable nor appropriate to subject such operational judgments to notice and comment rulemaking.

Comment: Two commenters complained that the regulation does not indicate how we will determine what constitute duplicative review activities. One commenter recommended that we place the burden on the M+C organization to demonstrate how the accrediting process duplicates a specific external review activity. The commenter advocated that such demonstration include full disclosure of the standards and protocols used by the accrediting organization to reach accreditation decisions, a comparison of the actual survey data and reports, and information about the composition of the review teams. The commenter recommended that the M+C organization's enrollees be informed when the organization seeks exemption from external review activities, and that they be given an opportunity to comment upon the application for exemption. Finally, the commenter asked that the exemption

not be granted for more than one year at a time, and not be granted if the accreditation results in nonpublic reports.

Response: We intend to make the decision as to which external review activities an M+C organization accredited by an approved accreditation organization is exempt from as part of the process of approving the accreditation organization. The accreditation organization will supply us with all the information necessary to determine where its activities overlap with those of the review organization. The exemption will be reviewed as the accreditation process or scope of work changes. We are revising §422.154(b)(2) to make it clear that an exemption based on duplicative review under the accreditation process will be made only with respect to approved accreditation activities because these are the only activities we will be in a position to evaluate when determining whether there is duplication.

With respect to the commenter's advocating that we require "disclosure" by accreditation bodies of their protocols, and disclosure to beneficiaries of decisions on duplication (with an opportunity to comment), we do not believe these steps are warranted. The quality standards that apply to M+C organizations apply without regard to whether duplication has been found. A beneficiary has access to detailed information on these standards, which are all public. We believe that it should not make a difference to the beneficiary whether our judgment that

these standards are being satisfied is based on the findings of an accreditation body, HCFA, or an external review entity, as long as HCFA is responsible for ensuring that they are met.

We do not see the point in limiting exemptions to a year, if there is no reason to believe that the factors we will consider in making a decision on duplication will be changing.

On the issue of "nonpublic reports," we expect that the public will have access to the same quality information for all M+C organizations, without regard to whether specific review activities were found to be duplicative.

Comment: One commenter asked that we designate the PROs as review organizations in the regulation text, and not simply in the preamble.

Response: We currently have the authority to contract with non-PRO entities to perform functions of the type described in part 466, and although we have not chosen to exercise this authority at this time, we believe that it is important to maintain it. There may come a time when we decide that it is desirable to allow other entities to serve as review organizations; thus, we are not designating the PRO as the review organization in the regulation text.

Comment: One commenter expressed concern that the regulation does not explicitly obligate M+C organizations to cooperate with review organizations' investigation of quality of

care complaints. This commenter suggested that §422.154(b)(1)(ii) be revised to require that the M+C organization provide to the review organization all pertinent data it needs to carry out its reviews and make its determinations, including assessments of beneficiary quality of care complaints.

Response: Because assessments of beneficiary quality of care complaints are among the determinations that the review organization makes, we believe the existing requirement as written is sufficient to compel M+C organizations to cooperate with any complaint investigations conducted by the review organization.

Comment: One commenter asked that M+C organizations not be responsible for the cost of the external review.

Response: HCFA pays the cost of the external review, not the M+C organization. The M+C organization might initially bear the cost of duplicating medical records requested by the review organization, but the organization will be reimbursed for that cost.

Comment: Two commenters stressed the importance of public access to external review results. One of the commenters specifically asked that we require review organizations to release an annual report to the public summarizing their

activities and the results of M+C organization performance improvement projects.

Response: In the PRO manual, there are detailed requirements relating to an annual report, which the PRO is required to send to the State and local offices of aging, and to senior citizen groups. In addition, the PRO is obligated to make the report available to beneficiaries upon request. Because specialized quality review organizations (the M+C/QROs), rather than PROs, will be evaluating the results of M+C organization performance improvement projects, the PRO annual report will not include this information. However, we will ensure that there is a vehicle to inform the public of whether M+C organizations have met the requirement for achieving significant improvement.

Comment: One commenter asked that the regulation require that the external review address each component of the health delivery system, including laboratory services.

Response: Our own monitoring will assess the adequacy of an organization's health delivery system, of which we acknowledge laboratory services are a part.

Comment: One commenter asked that we define the adequate space and data requirements in paragraph (b)(1).

Response: We are not defining "adequate space" because the PRO's need for room in which to work could vary with each review. As for data requirements, they are generally stated in

§476.102(c). This paragraph requires health care practitioners and providers to maintain evidence of the medical necessity and quality of health care services provided to Medicare patients as required by the PROs.

#### 4. Deemed Compliance Based on Accreditation (§422.156)

Section 1852(e)(4) of the Act gives the Secretary the authority to deem that an M+C organization meets certain requirements if the M+C organization is accredited and periodically reaccredited by a private organization under a process that we have determined ensures that the M+C organization, as a condition of accreditation, meets standards that are no less stringent than the applicable HCFA requirements.

Section 422.156(a) of the M+C regulations specifies the conditions under which an M+C organization may be deemed to meet the HCFA requirements permitted to be deemed under section 1852(e)(4) of the Act.

The current version of §422.156(b) specifies the requirements that could be deemed under the original BBA deeming provisions. In accordance with those BBA provisions, these included only the quality assessment and performance improvement requirements of §422.152, and the requirements of §422.118 related to confidentiality and accuracy of enrollee records. As discussed in section I. C. of this preamble, the BBRA amended section 1852(e)(4) of the Act to provide for deeming of

additional requirements. An M+C organization accredited by an approved accreditation organization could be deemed to meet any or all of the requirements specified in section 1852(e)(4) of the Act, depending on the specific requirements for which its accreditation organization's request for approval was granted.

Section 422.156(c) establishes when deemed status is effective. Deemed status is effective on the later of the following dates: the date on which the accreditation organization is approved by us, or the date that the M+C organization is accredited by the accreditation organization.

Section 422.156(d) establishes the obligations of deemed M+C organizations. An M+C organization deemed to meet Medicare requirements must submit to surveys to validate its accreditation organization's accreditation process, and authorize its accreditation organization to release to us a copy of its most current accreditation survey, together with any information related to the survey that we may require (including corrective action plans and summaries of unmet HCFA requirements.)

Section 422.156(e) addresses removal of deemed status. We will remove part or all of an M+C organization's deemed status if: (1) we determine, on the basis of our own survey or the results of the accreditation survey, that the M+C organization does not meet the Medicare requirements for which deemed status was granted; (2) we withdraw our approval of the accreditation

organization that accredited the M+C organization; or (3) the M+C fails to meet the requirements of paragraph (d) of this section.

Finally, §422.156(f) explains that we retain the authority to initiate enforcement action against any M+C organization that we determine, on the basis of our own survey or the results of the accreditation survey, no longer meets the Medicare requirements for which deemed status was granted.

In addition to expanding the types of requirements that are deemable, section 518 of the BBRA also specified procedural changes to the accreditation process which are also discussed in section I.C above and in several responses below. As noted above, these changes have been reflected in a revised version of §422.156.

The comments and responses regarding §422.156 are discussed below.

Comment: Several commenters expressed general support for the deeming provisions as stated in the regulation.

Response: The M+C deeming provisions are modeled on those that have been used successfully in original Medicare, and commenters have validated our belief that these provisions will work equally well in Medicare managed care.

Comment: One commenter was concerned that if we allow deeming, we will not be able to ensure access for disabled enrollees. This commenter recommended that we ensure that

accreditation organizations include in their review an assessment of an organization's ability to treat members with disabilities and complex care needs.

Response: We appreciate this comment, and agree that it is important that the needs of disabled enrollees not be overlooked. In evaluating whether standards imposed by an accreditation organization are at least as stringent as HCFA's, specifically QISMC Standard 3.1, we will take into account whether these standards account for the needs of disabled enrollees.

Comment: Two commenters recommended that we expedite the implementation of the deeming program.

Response: We recognize the value of deeming to M+C organizations and intend to proceed with deeming at the earliest opportunity. As a first step in this process, we will require that accreditation organizations develop crosswalks between their standards and the QISMC standards relating to the M+C requirements for which the organizations are seeking deeming approval. Only after we have revised the interim QISMC standards to reflect the changes made in this final rule and the final rule published February 17, 1999, will we have an accurate set of standards for use by the accreditation organizations in completing their crosswalks. We expect to release a revised set of QISMC standards shortly after publication of this final rule. Thirty days after publication we will begin accepting

applications from accreditation organizations. A Federal Register notice formally announcing this timetable is being published concurrently with this final rule.

Comment: Three commenters addressed the requirement that, as a condition of deemed compliance, an M+C organization be "fully accredited." The commenters believe this condition would be problematic, given that many accreditation organizations have multiple accreditation categories. One of the commenters, an accreditation organization, stated that this policy is "...a significant and substantive change from the current process under Medicare. At this time there exists a variety of accreditation levels..." not only within accreditation organizations but among them. A second accreditation organization complained that restricting deeming to only M+C organizations that have been "fully accredited" contradicts the stated policy of deeming on a standard-by-standard basis. It explained that requiring an M+C organization to meet all of an accreditation organization's standards decreases the potential savings and efficiencies associated with deeming.

Response: Because accreditation categories differ among accreditation organizations, we expect that "fully accredited" will have to be defined on an organization by organization basis. Fully accredited will generally mean that all elements within all the accreditation standards for which the accreditation

organization has been approved by HCFA have been surveyed and fully met or otherwise determined as acceptable without significant findings, recommendations, required actions or corrective actions. The commenter who complained that the requirement that an M+C organization be fully accredited is inconsistent with our intent to approve accreditation organizations on a standard-by-standard basis has misunderstood the requirement. The M+C organization must be fully accredited for only those standards for which the accreditation organization has been approved, not all of the accreditation organization's standards. We understand how the commenter misinterpreted the existing regulations, and we are revising §422.156(a)(1) to clarify this requirement.

Comment: One commenter pointed out that if an M+C organization chooses not to be accredited, we will perform a complete audit of its functions. Because there is no cost to the M+C organization for our audit, the commenter believes it would be to an M+C organization's advantage not to be accredited, because it would avoid the cost of accreditation as well as duplicate reviews (for example, an accredited M+C organization's grievance and appeal program would be reviewed both by the accreditation organization and by HCFA because the grievance and appeal requirements are not deemable). The commenter asked whether this interpretation is correct.

Response: The commenter's interpretation is correct, although there are benefits associated with accreditation, such as improved marketability, that we believe make accreditation attractive.

Comment: Many commenters addressed the scope of deeming. The majority of commenters supported the limited deeming reflected in the interim final regulation. One of these commenters cited as support for limited deeming a recent report regarding the problems associated with deeming based on private accreditation of hospitals. One commenter advocated the continued development and implementation of the "enhanced review" process begun several years ago. One commenter opposed limited deeming. This commenter, an accreditation organization, asserted that the regulation does a disservice to its clients as they are still subject to a our survey. Further, this accreditation organization complained that the regulation fosters "the very duplication of effort and stifling of innovation that the BBA sought to avoid by requiring deemed status."

Response: In recognition of the efficiencies associated with deeming, section 518 of the BBRA amended section 1852(e)(4) of the Act to provide for the deeming of additional requirements. Specifically, the additional deemable requirements are those related to the following sections of the Act: section 1852(b) (which relates to antidiscrimination); section 1852(d) (which

relates to access to services), section 1852(i) (which relates to information on advance directives), and section 1852(j) (which relates to provider participation rules). We are revising §422.156(b) to add these requirements.

We note that HCFA's oversight of managed care accreditors will be different from that of hospital accreditors, i.e., the JCAHO. Deeming based on JCAHO accreditation is explicitly required by statute, whereas potential M+C accreditors must demonstrate their ability to apply and enforce standards at least as stringent as our own as a condition of approval. In the event that a managed care accreditor fails to perform as promised, we retain the authority to withdraw its approval. Therefore, there are safeguards in place to prevent the situation that has arisen in hospital deeming from repeating itself in managed care.

Comment: Four commenters addressed the topic of approving accreditation organizations on a standard by standard basis as outlined in the regulation. Three commenters were in favor. One commenter asked if approving on a standard by standard basis means that we will "... approve an accreditation organization for some standards but not for others." One commenter contended that our decision to approve accreditation organizations on a standard by standard basis is "inconsistent with the need to reduce the duplication of effort." This commenter, an accreditation organization, recommended that accreditation organization

standards be assessed to determine if overall they equal or exceed HCFA's requirements. This commenter continued to state that "... approving individual standards will lead to a stifling of innovations and improvements over time."

Response: Section 518 of the BBRA has caused us to revise our approach to approving accreditation organizations. Originally, section 1852(e)(4) of the Act stipulated that "the Secretary shall provide that a Medicare+Choice organization is deemed to meet requirements" of certain subsections of the Act if the organization were accredited by an approved organization. The BBRA changed the provision to read that "the Secretary shall provide that a Medicare+Choice organization is deemed to meet all the requirements" (emphasis added) of certain cites within the Act. The result of the change is this: it is still possible for us to approve an accreditation organization for a subset of the deemable requirements alone; for instance, we may approve an accreditation organization for the quality assurance subset (which includes the quality assessment and performance improvement program requirements of §422.152) without approving it for any others. However, the accreditation organization must now have a comparable standard to every one of the M+C requirements within the quality assurance subset. Prior to enactment of the BBRA, an accreditation organization with only

some quality assurance standards equivalent to the M+C requirements would have been permitted to participate in deeming; HCFA would have monitored for compliance with the M+C requirements for which no equivalent accreditation organization standards existed. Now, because the BBRA requires, in essence, that HCFA deem an accredited M+C organization by subset, rather than by requirement, we can approve an accreditation organization only if it has a standard that meets or exceeds each of the M+C requirements of the subset. While this policy could limit the extent to which an accreditation organization may be involved in deeming, it could be viewed as simplifying the oversight process, since there is no longer the potential for HCFA and an accreditation organization to divide responsibility for monitoring an M+C organization's compliance with the requirements of the same subset. We have revised the introductory clause in §422.157(a) (discussed below) to reflect this BBRA change.

Comment: One commenter requested that public notice be given if an M+C organization's deemed status is removed or an accreditation organization's approval is withdrawn.

Response: We agree that when we withdraw an accreditation organization's approval, HCFA should give public notice because the information may influence the choice of accreditation organization made by M+C organizations seeking accreditation. We expect to give this notice by posting it on our website.

When we withdraw an accreditation organization's approval, we also remove the deemed status of all M+C organizations accredited by the organization. Upon removal of an M+C organization's deemed status, HCFA immediately assumes responsibility for ensuring that the organization meets our standards. Because beneficiaries are not at risk, and because notifying them of the loss of their M+C organization's deemed status could cause them to be concerned that they are at risk, we do not believe it is necessary or appropriate to so notify beneficiaries.

Comment: A few commenters addressed our authority under §422.156(e)(1) to remove deemed status on the basis of a review of accreditation survey results. One of the commenters, an accreditation organization, strongly disagreed with the provision, complaining that it "...would allow us to take the results of an accreditation survey and essentially ignore the decision of the accreditation organization without any independent data gathering." The commenter contended that the provision presumes that HCFA staff understand the accreditation requirements, and are better able to judge the performance of the M+C organization against those requirements than the accreditation organization's own surveyors. This commenter encouraged HCFA to conduct its own survey if we believe an M+C organization is not in compliance. If we reach a different

conclusion than the accreditation organization after its own survey, then the commenter believes that we would be justified in removing deemed status. Another accreditation organization expressed similar concern with §422.156(e)(1), stating that the regulation language could be used by us to "second guess the compliance determination using only the results of the accreditation survey." This commenter recommended limiting the removal authority to reflect this concern.

Response: We do not intend to overrule an accreditation organization's survey decision without doing our own investigation. If our own investigation reveals, however, that a condition is not met, we reserve the right to remove deemed status even when the accreditation organization has not removed accreditation with respect to that condition. In order to clarify the distinction between--(1) a removal of deemed status by HCFA, based on HCFA's own survey, and (2) a removal based on a determination of noncompliance by an accreditation organization as a result of its accreditation survey, we have revised §422.156(a) to separate these two situations. This should make it clear that we will not "second guess" the accreditation organization's conclusions based on its review without doing our own independent investigation.

#### 5. Accreditation organizations (§422.157)

In §422.157(a), we discuss three conditions for our approval of an accreditation organization. We may approve an accreditation organization if the organization applies and enforces standards for M+C organizations that are at least as stringent as Medicare requirements (as discussed above); the organization complies with the application and reapplication procedures set forth in §422.158, "Procedures for approval of accreditation as a basis for deeming compliance;" and, the organization is not controlled by the managed care organizations it accredits, as defined at §413.17.

Section 422.157(b) of the interim final rule describes notice and comment procedures. Because the approval of an accreditation organization could have broad impact upon large numbers of organizations, providers, and consumers, we are providing notice and comment opportunities similar to those provided in the fee-for-service arena.

Section 422.157(c) establishes ongoing accreditation organization responsibilities. These responsibilities largely parallel those currently imposed upon accreditors under original Medicare. One exception is the requirement at §422.157(c)(4) that an accreditation organization notify us in writing within 3 days of identifying, with respect to an accredited M+C organization, a deficiency that poses immediate jeopardy to the M+C organization's enrollees or to the general public.

Section 422.157(d) establishes specific criteria and procedures for continuing oversight and for withdrawing approval of an accreditation organization. Oversight consists of equivalency review, validation review, and onsite observation.

Section 422.157(d) states that an accreditation organization dissatisfied with a determination to withdraw our approval may request a reconsideration of that determination in accordance with subpart D of part 488 of this chapter. The comments and responses regarding §422.157 are discussed below.

Comment: One commenter recommended that HCFA, when making a determination based on its own survey or the results of an accreditation survey that an M+C organization does not meet Medicare requirements, "define the requirements, data collection tools, and scoring (including relative weights) guidelines" used to make the determination. The commenter explained that disclosure of such information is consistent with assuring beneficiaries and providers that HCFA determinations and surveys are objective and based on criteria that are public, relevant and valid.

Response: We agree with the need to make our process for making determinations available to the public. That is why materials such as our monitoring protocol are available to the public on HCFA's website, [www.hcfa.gov/medicare/mgdcar1.htm](http://www.hcfa.gov/medicare/mgdcar1.htm).

Comment: We received six comments requesting public disclosure of accreditation survey results. One commenter requested that we require in the regulation that enrollees be able to obtain from us their organization's accreditation survey results. An accreditation organization itself agreed with the need for public disclosure and stated that "If the accreditation is to be used for a public purpose, participation in Medicare, then we are accountable for the decision and the information upon which it was based."

Response: We agree that public disclosure of accreditation survey results is appropriate. If an accreditation organization does not have a policy for publicly disclosing accreditation survey results, it will be required to develop one as a condition of our approval.

Comment: An accreditation organization recommended that we provide accreditation organizations with quality-related information, for example, performance measurement data, quality improvement projects, etc.

Response: We concur with the importance of "two way communication," which is why we routinely publish or otherwise make available to interested parties the types of information referred to by the commenter, such as HEDIS results.

Comment: One accreditation organization contended that the monthly reporting requirements exceed our needs, and it

recommended that the regulation reflect our right to receive the information but not specify a reporting frequency until after information use and need is determined.

Response: We believe the reporting requirements of §422.157(c)(1) accurately reflect our need for information. The information that accreditation organizations are required to report and the time frames in which they are required to report it are based on requirements that have proven their usefulness and necessity in deeming under original Medicare. We have no reason to believe that the organizations that accredit M+C organizations should be held to a different standard.

Comment: Two commenters addressed the conflict-of-interest provision at §422.157(a)(3). One commenter stated that the provision is "so broadly drawn as to preclude managed care organizations from serving on the boards of accreditation organizations, or otherwise participating in the accreditation development process." This commenter requested that we clarify that such activities are permissible. The second commenter also objected to the conflict-of-interest provision as written, recommending that we focus instead on whether the accreditation organization has policies in place that separate individuals affiliated with an M+C organization from an accreditation decision impacting that organization. This commenter asked for a definition of "controlled" that allows M+C organizations to

participate in appropriate accreditation organization governance and policy making activities, but prohibits M+C organizations from having inappropriate influence on accreditation decisions affecting themselves.

Response: We believe it is important that no single or group of managed care organizations be allowed to exert undue influence over a private accreditation organization in any decision making process that would allow that single or group of organizations to benefit at the expense of others. However, we recognize the valuable role that representatives of managed care organizations may play in private accreditation organizations, and we agree that the regulation as written appears to prohibit a number of acceptable activities. Therefore, we are revising §422.157(a)(3) to require that an accreditation organization ensures that: (1) any individual associated with it who is also associated with an entity it accredits does not influence the accreditation decision concerning that entity; (2) the majority of the membership of its governing body is not comprised of managed care organizations or their representatives; and (3) its governing body has a broad and balanced representation of interests and acts without bias.

Comment: One commenter asked whether we must act on an accreditation organization's application for approval within 210

days, as is the case with respect to fee-for-service accreditation.

Response: The 210-day time frame that applies to accreditation under original Medicare is set forth in section 1865(b)(3) of the Act, and was not originally included by the Congress in section 1852(e)(4) of the Act. However, section 518 of the BBRA amended section 1852(e)(4) of the Act to add this requirement, and we are incorporating it into §422.158(e).

In addition, because we are now required to make our decision on an accreditation organization's application within 210 days, we are revising §422.157(b)(1) to restructure the provisions concerning timing and content of the Federal Register notice that solicits public comments on accreditation organization applications to allow for a comment period that is concurrent with HCFA's review. This process, also used by original Medicare, will give the public a meaningful opportunity to comment on the applications.

In the interim final rule, we modeled §422.157(b)(1) on the original Medicare deeming regulation at §488.8(b)(1). However, §488.8(b)(1) was written before section 1865(b)(3)(A) of the Act was amended to require 210-day turnaround on accreditation organization applications, and we are now in the process of revising §488.8 to conform with the Act. If we do not revise §422.157(b)(1) to follow original Medicare's model, we are

concerned that our review of the accreditation organization's standards will be so time consuming, there will be little time left within the 210 days for the public comment period.

Therefore, revised §422.157(b)(1) specifies that the Federal Register notice will announce our receipt of the accreditation organization's application for approval, describe the criteria we will use in evaluating the application, and provide at least a 30-day public comment period. Again, the timing and content of this notice are consistent with the way in which we solicit comments on accreditation organization applications in original Medicare deeming, pursuant to section 1865(b)(3)(A) of the Act.

Comment: One commenter argued that it is not appropriate for us to take action against an accreditation organization "irrespective of the rate of disparity" between certification by the accreditation organization and certification by us or our agent. The commenter agreed that accreditation organizations are "accountable to us and the public for the decisions they make and failure to properly assess the performance of the organizations they accredit should be grounds for action." However, the commenter complained that open-ended authority to withdraw an accreditation organization's approval regardless of the rate of disparity is inappropriate.

Response: It is an approved accreditation organization's responsibility to ensure that accredited M+C organizations meet

or exceed our standards. As per the regulation, if widespread or systematic problems are identified that indicate that an accreditation organization can no longer make that assurance, we reserve the right to take appropriate action, regardless of the disparity rate. However, we can assure the commenter that in Federal oversight of accreditation organizations, a variety of factors and measures are considered and utilized, only one of which is the disparity rate.

In response to the commenter's concern, we are requiring that accreditation organizations provide us annually with summary data relating to their accreditation activities and observed trends. These data will assist us in making a comprehensive assessment of accreditation organization performance, and will help ensure that our oversight decisions are well-informed and appropriate. This change appears at §422.157(c)(6).

Comment: One commenter requested that we clarify the term "enforces" as it is used in §§422.157(a)(1) and 422.158(a)(3)(iii)(C).

Response: An approved accreditation organization must apply and enforce standards that are at least as stringent as HCFA's requirements. By that, we mean that we expect the accreditation organization to assess compliance with the approved standards, and where it finds that an M+C organization is not in compliance, to ensure that corrective action is taken.

6. Procedures for Approval of Accreditation as a Basis for  
Deeming Compliance (§422.158)

The requirements of §422.158, which pertain to required application materials, the mechanics of the approval process, and the reconsideration of an adverse determination, are essentially restatements of the original Medicare requirements under §488.4.

Comment: One commenter disagreed with the provision that prohibits an accreditation organization that has requested reconsideration of a denial from filing a new application while the reconsideration is pending. The commenter believes that this provision will discourage accreditation organizations from challenging a denial and result in a denial of due process.

Response: An accreditation organization may request a reconsideration if it receives a denial of its application. This may be done by submitting a request for reconsideration, the requisite supplemental information, and any necessary supporting documentation. In lieu of the reconsideration, an accreditation organization may select the option of submitting a new application that has been revised to address the deficient areas that led to the initial denial. Therefore, the prohibition against simultaneously submitting a request for reconsideration and a new application does not deprive an M+C organization of the right to submit a new application.